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10/589,420	08/15/2006	Tsukao Yokoyama	YPO1.001APC	9866

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/589,420	Applicant(s) YOKOYAMA ET AL.	
	Examiner JAMES L. GRUN	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-20 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/13/06;10/23/06</u> . | 6) <input type="checkbox"/> Other: ____. |

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The disclosure is objected to because of the following informalities: the specification is replete with grammatical, idiomatic, and spelling errors too numerous to specifically point out and should be carefully revised. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification is objected to and claims 1-8 and 11-20 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are: (1) known and readily available to the public; (2) reproducible from the written description; or, (3) deposited in compliance with the criteria set forth in 37 CFR §§ 1.801-1.809.

It is unclear if cell lines which produce antibodies having the exact chemical identity and properties of the antibodies designated “NC1” are known and publicly available, or can be reproducibly isolated without undue experimentation. Accordingly, filing of evidence of the reproducible production of the cell lines and antibodies necessary to practice the instant invention or filing of evidence of deposit is required. Without a publicly available deposit of the

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above cell lines, one of skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: the claimed cell line; the cell lines which produce the chemically and functionally distinct antibodies claimed; and/or, the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event. For example, very different V_H chains can combine with the same V_L chain to produce antibody binding sites with nearly the same size, shape, antigen specificity, and affinity. A similar phenomenon can also occur when different V_H sequences combine with different V_L sequences to produce antibodies with very similar properties. These observations indicate that divergent variable region sequences, both in and out of complementarity-determining regions, can be folded to form similar binding site contours, which result in similar immunochemical characteristics. Therefore, it would require undue experimentation to reproduce the claimed monoclonal antibody species chemically as produced by the hybridoma designated "NC1". Note that an enabling disclosure for the preparation and use of only a few analogs of a product, or seemingly a single product herein, does not enable all possible analogs where the characteristics of the analogs are unpredictable. Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. (18 USPQ 2d 1027 (CAFC 1991)). A suitable deposit of the hybridomas would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See the criteria set forth in 37 CFR §§ 1.801-1.809.

If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty, that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and that the deposited biological materials will be replaced should they become non-viable, would satisfy the deposit requirement made herein.

If the deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR §§ 1.801-1.809, applicant may provide

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assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) the deposits were viable at the time of deposit; and,
- (e) the deposits will be replaced if they should become non-viable.

Applicant is also reminded that information regarding the deposits, such as the name and address of the depository, in addition to the accession numbers of the deposits and the date(s) of the deposits, **must** be added to the specification by means of filing an amendment as required by 37 CFR § 1.809(d).

Applicant is reminded that the written description provision of 35 USC 112 is severable from its enablement provision. In this regard, adequate written description requires more than a mere statement that a molecule is part of the invention and a reference to a potential method of isolating it. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of molecules by only their functional activity does not provide an adequate written description of the genus. The court indicated that although applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Alternatively, to provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties,

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functional characteristics when coupled with a known or disclosed structure/function correlation, or any combination thereof. In this case, the only factors present in the antibodies of the description and claims are an ability to bind an undefined epitope in the mixture of bovine renal glomeruli noncollagenous domains (NC1) of collagen and also to bind glomeruli of macaque monkeys and humans with nephritis. There is no identification of which or of any particular portion of the multiple chains of the bovine NC1 fraction that must be bound. There is no identification of the structure of the "NC1" antibody of the instant invention. In the absence of any guidance other than to the use of the "NC1" antibodies, one would not know or be able to predict or envision what structure or modifications were important for function. Knowledge of the partial structure of framework regions of immunoglobulins provides no guidance for the function of an antibody. Thus, applicant provides no disclosure of complete or partial structure identifying the genus and no structure/function correlation identifying the genus.

Therefore, only a deposit of the hybridoma producing the "NC1" antibodies has the potential to meet the written description and enablement provisions of 35 U.S.C. §112, first paragraph. The full breadth of the claims does not meet the written description and enablement provisions of 35 U.S.C. §112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 11-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-8 and 11-20, the acronym “NC1” should not be used until fully defined at its first occurrence in the independent claim, such as by --noncollagenous domain of collagen (NC1)--.

Claims 1, 3-5, 8, 9, 12, 14, 16, 17 and any claims dependent thereupon are, or appear to be or encompass, method claims and, as such, they should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting, and detecting. “Employing” or “using” are not valid method steps. These claims are indefinite because without any active, positive steps delimiting how the method is actually practiced it is unclear what method/process applicant is intending to encompass. The claims should also clearly state each component used in the method and the relationship of the various components, and should not be a mere cataloging of parts. The claims should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim.

In claims 2-4 and claims dependent thereupon, “characterized by” is improper claim language and is vague as to what is encompassed because it is not clear if “characterized” is open or closed claim language and therefore the term does not clearly set forth the metes and bounds of the invention for which applicant desires protection.

In claim 5, “the” live specimens lack antecedent basis.

In claim 8, “the” renal type IV or antigen lack antecedent basis.

In claim 9, “the” initial dose lacks antecedent basis.

In claim 12, it is believed --immunological-- was intended.

In claim 17 it is not clear what is encompassed by “positive pores.” It is believed -- dimer-- was intended.

The interrelationships of the components in claim 18 and claims dependent thereupon are not clear because it is not clear if blood or serum (or plasma) is being treated. In claim 19, “the” internal circulation lacks antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,

except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language;

Claims 3 and 5-8 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Borza et al. (J. Biol. Chem. 276: 28532, 2001).

Borza et al. elicited monoclonal antibodies to bovine glomerular basement membrane that bound to NC1 in ELISA and were also used in Western blotting reactions. The antibodies were used in affinity columns for purification of NC1 (a NC1 remover) and were used in immunoprecipitation assays with protein G-sepharose (an anti-NC1 antibody remover).

Claims 3 and 5-8 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Johansson et al. (J. Biol. Chem. 267: 24533, 1992).

Johansson et al. provided monoclonal and polyclonal antibodies to bovine glomerular basement membrane NC1 and used the antibodies in ELISA, Western blotting reactions, and in affinity columns for purification of NC1 (a NC1 remover). In the ELISA, immobilized NC1 was used to capture the antibodies (an anti-NC1 antibody remover).

Claim 6 is rejected under 35 U.S.C. § 102(b) as being anticipated by Oftshun et al. (US 5871649) in light of Sugihara et al. (J. Pathol. 178: 352, 1996).

Oftshun et al. teach an affinity membrane device for the removal of deleterious solutes, such as anti-NC1 autoantibodies inherently (in light of Sugihara et al.) found in the blood of Goodpasture's syndrome patients (see e.g. col. 19).

Claim 9 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kitchell et al. (US 5,656,298).

Kitchell et al. teach immunization with a primer dose and a delayed release booster dose five times that of the primer dose (see e.g. col. 14 and Fig. 7).

Claim 9 is rejected under 35 U.S.C. § 102(e)(2) as being clearly anticipated by Chambers et al. (US 6696281).

Chambers et al. teach immunization with a primer dose and boosting with a higher dose than that of the primer dose for vaccination (see e.g. col. 62, Table 8).

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ninomiya et al. (J. Cell Biol. 130: 1219, 1995) teach monoclonal antibodies specific for NC1 peptides and their use in various immunoassays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
June 26, 2008

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641